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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,595	09/29/2004	Kaoru Asano	Q83447	3089

23373 7590 03/15/2007

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EXAMINER	
WHALEY, PABLO S	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,595	ASANO ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006 and 27 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-37* is/are pending in the application.

4a) Of the above claim(s) *23-25,27 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 22, 26, 28-30, and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/17/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

SUPPLEMENTARY ELECTION

Applicant's election of SEQ ID No. 14 with traverse, filed 11/27/2006, is acknowledged. It is noted that applicant elected SEQ ID NO: 1 and Species B (iii) drawn to the variant substitution at position 4037 of SEQ ID No. 1, without traverse in the response filed 1/27/2006. The specie election drawn to Specie A (iii) was withdrawn for the expedience of prosecution.

In response to applicant's arguments with regard to the examination of SEQ ID NOs 2-16, the Examiner maintains that these sequences are patentably distinct because they are unrelated sequences. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

CLAIMS UNDER EXAMINATION

Applicant's remarks, filed 8/17/2006, have been fully considered. Applicant's amendment, filed 08/17/2006, introduced new claims 21-37 and cancelled claims 1-20. Claims herein under examination are newly added claims 21, 22, 26, 28-30, and 32-37, as they read upon the elected sequences (SEQ ID NO: 1 and SEQ ID NO: 14) and the elected variation position (Species B) drawn to the substitution at position 4037 of SEQ ID No. 1. Claims 23, 24, 25, 27, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species of non-elected variation positions, there being no allowable generic or linking claim.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as

necessitated by amendment. They constitute the complete set presently being applied to the instant application.

PRIORITY

Priority to Foreign Application JAPAN 2002-93443, filed 03/29/2002 is not granted as no translation of this document has been received. It is noted that the certified copy filed 09/29/2004 is written in Japanese.

DRAWINGS

Drawings filed 9/29/2004 have been accepted.

CLAIM REJECTIONS - 35 USC §112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, 26, 28-30, and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claims. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below which leads to the determination that the above claim lacks enablement due to undue experimentation being required to make and use the invention.

Claims 21, 22, 26, 28-30, and 32-37 are generally directed to a method for determining a risk for glaucoma in a subject. Claim 21 recites critical limitations directed to steps comprising (a) assaying at least two polynucleotide variations in a sample polynucleotide obtained from a subject, and (b) determining said risk based on detection of said at least two polynucleotide variations in said sample polynucleotide. In the instant case, the claimed subject matter lacks enablement for the following reasons:

Regarding (a): It is unclear how the applicant has determined that the claimed variations at positions 4037 and 4346 (of the MYOC gene) are actually associated with an elevated risk of glaucoma in a subject. No association studies or experimental evidence was provided to support these assertions. Prior art teaches the association of MYOC polymorphisms with glaucoma using probands shown by autoradiographs of affected patients and unaffected controls, as well as dye-terminator sequencing results, methods for predicting protein secondary structure, and association studies [Rozsa et al., Fig. 3, Fig. 4, and Table 3]. The specification as

filed does not provide equivalent supporting data. Prior art also teaches that there may be other mutations of the MYOC gene, such as the myosin-like domain, that are associated with retinal dysfunction [Kubota et al., p. 399, Col. 1, ¶ 2], which further supports undue experimentation as one of skill in the art would need to verify that the claimed variant positions are actually associated with an elevated risk for glaucoma. [Wands factors (2), (3)].

Regarding (b): The specification does exemplify the claimed method by presenting results of a study [Table 2], wherein 11 patients and 2 non-patients (i.e. controls) having variations at base positions 4037 and 4346 were examined for variations at other positions. However, these results are not deemed to be valid as no statistical power studies were provided by applicant that serve to illustrate that the sample size used in the study was one that would yield a statistically significant result. Thus, one of skill in the art would have to complete the appropriate power studies before practicing the claimed method, requiring undue experimentation. Furthermore, it is noted that the "non-patients" 1 and 2 (i.e. controls) both exhibited variations at base positions 4037 and 4346, which the applicant claims are indicative of a risk for glaucoma (See Table 2 below).

(Table 2)

Base position	194	199	324	1051	1084	1627	1685	1756	1853	2830	3371	4037	4346
Patient 1	*				*	*						*	*
Patient 2	*				*	*						*	*
Patient 3	*				*	*						*	*
Patient 4												*	*
Patient 5												*	*
Patient 6												*	*
Patient 7												*	*
Patient 8												*	*
Patient 9												*	*
Patient 10				*			*	*	*				
Patient 11				*			*	*	*				
Non-patient 1												*	*
Non-patient 2												*	*

As the controls themselves contain the variations at base positions 4037 and 4346, which are being used as indexes for the prediction of glaucoma, it is unclear how one of skill in the art could reasonably arrive at a valid result.

Therefore, given the nature of the instantly claimed invention, and for reasons set forth above, one skilled in the art would require undue experimentation to predictably practice the instantly claimed invention. [Wands factors (1), (2), (6), (7)].

CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3/1/07